UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

MEIJER, INC. and MEIJER DISTRIBUTION, INC., on behalf of themselves and all others similarly situated, **Plaintiffs,** **v.** **FERRING B.V., FERRING PHARMACEUTICALS, INC. and AVENTIS PHARMACEUTICALS, INC.,** **Defendants.**	**Civil Action No.** 05 CV 2237 **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiffs, on behalf of themselves and the class defined below, bring this antitrust action against Defendants Ferring B.V., Ferring Pharmaceuticals, Inc. and Aventis Pharmaceuticals, Inc., and allege as follows based upon personal knowledge as to matters relating to themselves and upon the investigation of their counsel and information and belief as to all other matters:

NATURE OF THE CASE

1. This case arises from Defendants' unlawful scheme to maintain illegally its monopoly in the United States market for the tablet form of its antidiuretic drug sold under the brand name DDAVP ("DDAVP") and its AB-rated generic equivalents. Desmopressin Acetate is the generic name for DDAVP.

2. As alleged in greater detail herein, Defendants engaged in a scheme which involved the commission of fraud and/or inequitable conduct before the United States Patent Office ("PTO") in order to obtain a patent, U.S. Patent No. 5,407,398 (the "'398 patent") which, in the absence of the fraud, would not have issued. Defendants then proceeded to procure improperly the listing of that fraudulently obtained patent in the FDA's Orange Book in order to be able to assert patent infringement claims against and block the market entry of any potential

generic competitor who sought FDA approval for a competing generic version of DDAVP. Knowing that the '398 patent was obtained by fraud and/or inequitable conduct, Defendants proceeded to institute litigation against at least one potential generic competitor, knowing that filing such litigation would automatically prohibit the FDA from granting approval to any of the generic manufacturers for up to 30 months.

3. Defendants illegally and intentionally manipulated the litigation provisions of the 1984 amendments to the Food, Drug, and Cosmetic Act added by the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act or Amendments. *See* Pub.L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271(e)). As many courts have recognized, these amendments were principally designed to streamline the process by which generic drugs are brought to market.[1]

4. Defendants knew full well that under the Hatch-Waxman Amendments the *mere filing* of the patent litigation would bar the FDA from granting marketing approval to any of the competing generic companies for up to 30 months, even though the patent was fraudulently obtained and the patent litigation was baseless. Thus, even though Defendants' patent was ultimately exposed as invalid in a detailed opinion by the United States District Court for the Southern District of New York, Defendants were able to block generic competition simply by listing the fraudulently obtained patent in the Orange Book and then filing and pursuing the patent litigation in the federal courts.

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[1] *See, e.g., Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997). "[T]hrough the Amendments, 'Congress sought to get generic drugs into the hands of patients at reasonable prices – fast.'" *Andrx Pharm., Inc v. Biovail Corp.*, 266 F.3d 799 (D.C. Cir. 2001) (quoting *In re Barr Laboratories, Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)). *See also Mylan Pharm. v. Shalala*, 81 F. Supp. 2d 30, 32 (D. D.C. 2000) ("The stated purpose of the legislation was to 'make available more low cost generic drugs,'" quoting H.R.Rep. No. 98-857, pt. 1., at 14 (1984)).

5. As a result of its unlawful acts, Defendants have: (1) unreasonably restrained, suppressed, and eliminated competition in the market for DDAVP and its generic equivalents; and (2) illegally maintained its monopoly in the market for DDAVP and its generic equivalents.

6. Absent Defendants' unlawful conduct, less expensive generic versions of DDAVP would have been on the market much earlier. Through its unlawful conduct, Defendants illegally deprived Plaintiffs (and the other direct purchasers who comprise the class alleged herein) of access to substantially lower-priced generic versions of DDAVP, thereby causing Plaintiffs and the Class to overpay for DDAVP by hundreds of millions of dollars.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this civil action pursuant to 28 U.S.C. §§ 1331 and 1337.

8. Venue is proper in this Court under 28 U.S.C. § 1391 and 15 U.S.C. § 22 because: (1) Defendants transacts business, committed an illegal or tortious act, and/or is found within this district; and (2) a substantial portion of the affected trade and commerce described below has been carried out in this district.

PARTIES

9. Plaintiffs Meijer, Inc. and Meijer Distribution, Inc. (collectively "Meijer") are corporations organized under the laws of the State of Michigan, with their principal places of business in Grand Rapids, Michigan. Meijer is the assignee of the claims of the Frank W. Kerr Co., which, during the Class Period, as defined below, purchased DDAVP directly from one or more Defendants.

10. Defendant Ferring B.V. is a privately held company organized under the laws of the Netherlands.

11. Defendant Ferring Pharmaceutical, Inc. (hereinafter referred to collectively with Ferring B.V. as "Ferring") is a New York corporation with its principal place of business at 400 Rella Boulevard, Suite 300, Suffern, New York. Ferring Pharmaceutical, Inc. is a subsidiary of Defendant Ferring B.V.

12. Defendant Aventis Pharmaceuticals, Inc. ("Aventis") is a Delaware corporation with its principal place of business at 300 Somerset Corporate Boulevard, Bridgewater, New Jersey.

INTERSTATE TRADE AND COMMERCE

13. During all or part of the Class Period, one or more Defendants manufactured and sold substantial amounts of DDAVP in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

14. At all material times, DDAVP manufactured and sold by one or more Defendants was shipped across state lines and sold to customers located outside its state of manufacture.

15. During all or part of the Class Period (defined below), Defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of DDAVP.

16. In furtherance of its efforts to monopolize and/or restrain competition in the market for DDAVP its generic equivalents, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel.

17. Defendant's efforts to monopolize and restrain competition in the market for DDAVP alleged herein has substantially affected interstate and foreign commerce.

CLASS ALLEGATIONS

18. Plaintiffs brings this action on behalf of itself and the following class:

> All persons and entities in the United States who purchased DDAVP in tablet form directly from Defendants at any time from December 13, 2002 through the present (the "Class Period"). Excluded from the class are defendants, their parents, employees, subsidiaries and affiliates, and federal and state government entities (the "Class").

19. The Class is so numerous that joinder of all members is impracticable. Plaintiffs believe that the Class numbers one hundred or more.

20. There are questions of law or fact common to the Class, including:

a. whether Defendants maintained monopoly power in delaying generic entry;

b. whether the patents described herein where obtained through fraud or inequitable conduct;

c. whether Defendants' litigation asserting infringement of its patents described herein was baseless;

d. whether Defendants' actions illegally maintained its monopoly power;

e. whether Defendants' conduct caused antitrust injury to the business or property of its direct purchaser customers.

21. These and other questions of law and fact are common to the members of Class and predominate over any questions affecting only individual members.

22. Plaintiffs' claims are typical of the claims of the Class because all Class members, including Plaintiffs, sustained antitrust injury in the same way as a result of Defendants' wrongdoing, and the claims of each Class member arise out of the same nucleus of operative facts and are based on the same legal theories.

23. Plaintiffs will fairly and adequately represent and protect the interests of the Class. Plaintiffs have retained counsel who are experienced in class action and antitrust litigation, and plaintiffs have no interest in this litigation that is adverse to, or in conflict with, the interests of the other members of the Class.

24. A class action is superior to the other available methods for the fair and efficient adjudication of this controversy. Plaintiffs know of no difficulty that will be encountered in the management of the claims advanced by the Class that would preclude class certification.

BACKGROUND
Federal Regulation of Prescription Drugs

A. New Drug Applications

25. The statute regulating the manufacture and distribution of drugs and medical devices in the United States is the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.* (the "FD&C Act"). Under the FD&C Act, approval by the FDA, the governmental body charged with the regulation of the pharmaceutical industry, is required before a company may begin selling a new drug in interstate commerce in the United States. 21 U.S.C. § 355(a). Premarket approval for a new drug must be sought by filing a new drug application ("NDA") with the FDA under § 355(b) of the FD&C Act demonstrating that the drug is safe and effective for its intended use.

26. New drugs that are approved for sale in the United States by the FDA are typically covered by patents, which provide the patent owner with the right to seek to exclude others from making, using and/or selling (depending on the scope of the patent) that new drug in the United States for the duration of the patents, plus any extension of the original patent period ("FDA Exclusivity Period") granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 ("Hatch-Waxman Act").

27. Pursuant to 21 U.S.C. § 355(b), in its NDA the pioneer drug manufacturer must list all patents that claim the drug for which FDA approval is being sought, or that claim a method of using the drug, and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug. Once the NDA is approved by the FDA, any claimed patents must be listed with the NDA in a publication known as the Approved Drug Products With Therapeutic Equivalence Evaluations. This publication is commonly referred to as the "Orange Book."

28. Federal regulations impose strict limitations on the types of patents that an NDA holder can submit to the FDA for listing in the Orange Book. *See generally* 21 C.F.R. § 314.53. One such limitation is imposed by 21 C.F.R. § 314.53(b), which explicitly prohibits NDA holders from listing any patent in the Orange Book unless a claim of infringement could reasonably be asserted on the basis of such a patent.

29. Despite the FDA regulations that limit the types of patents that NDA holders can list in the Orange Book, it has become common for brand companies to list any and every patent they can obtain in the Orange Book so as to force generic manufacturers to file what, as described below, is commonly known as a Paragraph IV certification, and the FDA does not police this practice. The FDA employs no adjudicatory or other process to determine whether a patent submitted by an NDA holder qualifies for listing under the applicable regulations. Indeed, the FDA has stated that it lacks the resources and expertise to review the patents submitted in connection with NDAs. *See* 59 Fed. Reg. 50338, 50343 (Oct. 3, 1994) ("FDA does not have the expertise to review patent information . . .").

30. As a result, as numerous courts have recognized, the FDA's role in the patent listing process is purely ministerial, and it relies entirely upon the good faith of the NDA holder submitting the patent for listing.

B. Generic Drugs

31. Generic drugs are drugs that the FDA has found to be bioequivalent to their corresponding brand name drugs. A generic drug provides identical therapeutic benefits and has the exact same side effects and safety profile as its corresponding brand name drug. Generic drugs invariably cost substantially less than the branded drugs to which they are bioequivalent. Typically, the first generic version of a brand name drug is sold at a substantial discount to the brand, followed by increasingly steeper discounts as more generics enter the market.

32. Under the Hatch-Waxman Act, a generic drug manufacturer may seek expedited FDA approval to market a generic version of a brand name drug with an approved NDA by filing an Abbreviated New Drug Application ("ANDA") pursuant to 21 U.S.C. § 355(j). An ANDA relies on the safety and efficacy data already filed with the FDA by the manufacturer of the equivalent brand name drug.

33. After an applicant has submitted its ANDA to the FDA it must file a patent certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii). There are four different types of certifications:

I. The brand name manufacturer has not filed patent information with the FDA (a "Paragraph I Certification");

II. The patent or patents filed in the Orange Book have expired (a "Paragraph II Certification");

III. The patent will expire on a date in the future, and the generic manufacturer does not seek to market its generic version of the drug prior to the date of expiration (a "Paragraph III Certification"); or

IV. The patent is invalid or not infringed by the generic manufacturer's product (a "Paragraph IV Certification").

21 U.S.C. § 355(j)(2)(A)(vii).

34. A generic drug applicant must serve the branded drug company with a copy of a certification under paragraph IV. The Paragraph IV Certification constitutes a "technical act of infringement" under Hatch Waxman which creates jurisdiction in the federal courts to entertain a patent infringement action, and gives the NDA holder forty-five days from the date of the notice to institute such an action against the generic manufacturer under 35 U.S.C. § 271(e)(2). *See* 21 U.S.C. § 355(j)(5)(B)(iii). If such a suit is initiated, the FDA's approval of the ANDA is automatically stayed for up to thirty months. 21 U.S.C. § 355(j)(5)(B)(iii).

35. The mere filing of an infringement action in response to a Paragraph IV certification, regardless of the action's underlying merit, gives the brand-name company the functional equivalent of a self-effectuating preliminary injunction blocking the entry of a generic competitor, without the brand company ever having to establish likelihood of success on the merits, irreparable harm, balance of hardships or the public good. Indeed, as a practical matter the brand name company *wins the lawsuit simply by filing it*, as it automatically protects its monopoly for up to two and a half years while the infringement action grinds through the court system. This creates a strong incentive to file suit against the ANDA filers because there are no disgorgement provisions for profits earned during the thirty month period of exclusivity if a court eventually determines that the suit was without merit.

36. An improper Orange Book listing also has additional anti-competitive effects because the first generic company to file an ANDA with a Paragraph IV Certification is, upon FDA approval, granted a 180-day period of exclusivity in relation to other generic manufacturers. 21 U.S.C. § 355(j)(5)(B)(iv). This 180 day exclusivity against other generic competitors is awarded to the first Paragraph IV filer regardless of whether or not the brand company institutes pre-approval patent infringement litigation in response to the Paragraph IV certification. Absent an improper Orange Book listing, no Paragraph IV certification would be required and, thus, no generic company would receive 180-day exclusivity.

37. Defendants were at all times fully familiar with their ability to delay the entry of generic competition by the improper manipulation of the patent listing and pre-approval litigation provisions of the Hatch-Waxman Amendments.

Defendants' Fraudulent Prosecution of the '398 Patent

A. The Original DDAVP Patents

38. In 1969, the PTO issued Patent No. 3,454,549 (the "'549 Patent") entitled "Desamino-Arginine-Vasopressin" which claimed the compound and process of making a synthetic version of the naturally occurring human hormone vasopressin. The claimed synthetic version replaced the terminal amino group in naturally occurring vasopressin with a hydrogen atom. The resulting claimed invention was a synthetic compound that had three times the antidiuretic effect of naturally occurring vasopressin.

39. In 1970, the PTO issued Patent No. 3,497,491 (the "'491 Patent") entitled "1-Deamino-8-d-Arginine Vasopressin" or "DDAVP" which claimed a polypeptide of vasopressin functioning as a targeted antidiuretic for the treatment of diabetes insipidus.

40. In 1977, Ferring received approval from the FDA to market an intranasal formulation of DDAVP as an antidiuretic. Shortly thereafter, Aventis obtained approval to market the same nasal formulation and eventually obtained approval to market an injectable version of DDAVP.

41. By 1990, both the '549 Patent and the '491 Patent had expired and the inventions claimed therein had entered the public domain. In anticipation of losing patent exclusivity on the DDAVP compound, Ferring submitted patent application serial number 809,937 that would ultimately issue as the '398 patent (the "'398 Patent Application") on December 17, 1985. The '398 Patent Application attempted to patent a form of DDAVP that was gastro-intestinally absorbable, i.e. a tablet form of DDAVP. If successful, the '398 Patent Application would have given Ferring renewed exclusivity in the sale of DDAVP products because Ferring would be the only company allowed to market the tablet form of DDAVP. Because tablet forms of prescription drugs are typically more popular than nasal or injectable versions, the '398 Patent Application was a significant business opportunity for Ferring.

B. Duty Of Candor and Good Faith in Dealing with the Patent Office

42. Rules governing patent prosecution impose a duty of candor and good faith on those dealing with the Patent Office, "which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56. The rule provides that: "Information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes

in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability."

43. As explained in more detail below, Ferring knowingly provided false and misleading information to the PTO in order to overcome the PTO's legitimate rejection of Ferring's attempt to claim an invention that was plainly anticipated by the previous DDAVP patents. With an intent to mislead the PTO, Ferring submitted declarations from ostensibly independent experts during the '398 patent prosecution when, in fact, those experts were at all relevant times undisclosed consultants to Ferring. Had Ferring not knowingly violated its duty of candor and good faith in dealing with the PTO, the '398 patent would not have issued.

C. Ferring's Wrongful Conduct in Obtaining the '398 Patent

44. The two inventors listed on the '398 Patent Application were Dr. Hans Vilhardt, a former research director at Ferring, and Mr. Helmer Hagstam, who was then the technical director at Ferring. The inventors assigned their rights in the application to Ferring.

45. After submitting the '398 Patent Application on December 17, 1985, Dr. Vilhardt and his attorney appeared at a preliminary interview with PTO Examiners on May 28, 1986, during which they discussed the '398 application and prior art, in particular, the '491 Patent and the '549 Patent.

46. The examiner's written summary of the interview states that Dr. Vilhardt and his attorney argued to the examiner "that prior art does not teach administration via stomach route and that peroral implies 'buccal' etc., and that one skilled in the art would not think otherwise." It also states that the applicants agreed to "consider amending the claims and filing declarations" and the examiner agreed to wait two weeks before giving a first action. The Examiner also suggested that applicants obtain evidence from a non-inventor which supported Dr. Vilhardt's

understanding that the term "peroral" in the '491 patent meant "sublingual or buccal" administration only, and not through the stomach.

47. On June 12, 1986, Ferring submitted a preliminary amendment, which added three new claims, and also submitted four declarations in support of issuing the '398 patent. Of the four declarations, Dr. Vilhardt submitted two, Dr. Czernichow submitted one and Dr. Miller submitted one. Each of these declarations were submitted with CV's attached. Dr. Czernichow's and Dr. Miller's declarations asserted that one skilled in the art who read the '491 Patent line describing peroral administration in connection with DDAVP would conclude that the term "peroral" referred to sublingual and/or buccal administration of DDAVP, and not to oral administration for gastrointestinal absorption. The CV of Dr. Czernichow did not disclose any relationship with Ferring or interest in the '398 Patent Application, although Dr. Vilhardt did disclose such interest.

48. On November 20, 1986, the PTO rejected the '398 Patent Application as anticipated by or obvious in light of the '491 patent.

49. On May 20, 1987, Ferring filed a request for reconsideration, arguing that the'491 patent did not expressly, impliedly or inherently teach the claims of the '398 Patent Application. Ferring submitted several articles relating to the subject matter in support of its position that those skilled in the art would not find the '398 patent obvious in light of the '491 Patent.

50. On August 14, 1987, the PTO again rejected the '398 Patent Application as anticipated by or obvious in light of the '491 patent.

51. Ferring appealed the PTO' decision on November 13, 1987. Ferring's brief included a copy of Dr. Czernichow's declaration, again not disclosing any relationship with Ferring or interest in the '398 Patent Application.

52. On September 21, 1990, the Board of Patent Appeals and Interferences affirmed the examiner's rejection of the '398 patent, concluding that the "peroral" recitation in the '491 patent coupled with the knowledge of the prior art, disclosed in Vavra, is suggestive of and anticipated the oral administration of DDAVP for gastrointestinal absorption in humans. The 1974 Vavra study involved the administration of desmopressin to rats by stomach gavage and showed that DDAVP caused antidiuresis in rats.

53. After review of the Board's decision rejecting the claims, Dr. Vilhardt wrote to the patent attorney that "everything now depends on our ability to deal with the Vavra paper." In preparing to "deal" with the Vavra paper, Vilhardt contacted at least two Ferring consultants regarding additional declaration evidence: Dr. Iain Robinson and Professor Barth. Both Robinson and Barth signed declarations in support of Vilhardt's positions. In addition, at some point during the '398 prosecution, Dr. Vilhardt also sought declarations from two other Ferring consultants, Professor Leonard Share, and Professor Besser.

54. On November 21, 1990, Ferring responded to the rejection by the Board of Patent Appeals by filing an amendment after appeal. Along with the amendment, Ferring filed five declarations submitted by Dr. Vilhardt, Dr. Miller, Dr. Czernichow, Dr. Robinson and Dr. Barth.

55. On April 8, 1991, the PTO issued a Notice of Allowability, allowing the '398 patent which issued on September 10, 1991. The invention disclosed and claimed in the '398 Patent is an orally effective form of desmopressin designed to be absorbed by the body through the gastrointestinal tract.

D. Unbeknownst to the PTO, Drs. Czernichow, Barth, and Robinson Were Paid Consultants of Ferring

56. Unbeknownst to the PTO, Drs. Czernichow, Barth, and Robinson, all of whom submitted crucial 'noninventor' declarations in support of the '398 patent application, were paid

consultants of Ferring. Dr. Czernichow submitted a declaration in 1986, and Drs. Czernichow, Barth and Robinson each submitted declarations in 1990, after the Board of Patent Appeals affirmed the examiner's earlier rejections.

57. The first Czernichow declaration was dated June 4, 1986, and was in direct response to the examiner's request for non-inventor declarations regarding the meaning of "peroral." In it, he states that the '491 patent did not teach him, and opined that it would not teach others skilled in this art to administer DDAVP in oral dosage form for gastrointestinal absorption by humans and that the meaning of "peroral" administration in the '491 patent meant that DDAVP could be administered through the mouth for sublingual or buccal absorption. Dr. Czernichow's second declaration was submitted in 1990, and addressed the Vavra reference by the Board of Patent Appeals.

58. Dr. Czernichow's CV does not mention any affiliation with Ferring, but he was a Ferring consultant and received research funding from Ferring from 1985 to 1986, and again from about 1988 to 1990, the same time period during which he submitted his declarations in support of the '398 patent application.

59. Dr. Iain Robinson, a neuroendocrinologist, filed a declaration in support of the '398 patent in November of 1990, which specifically addressed the Vavra reference by the Board of Patent Appeals after Plaintiff's appeal of the rejection. Dr. Robinson was employed as a pre-clinical research director at Ferring from 1985-1986, and during his tenure as research director, Ferring sponsored Dr. Vilhardt's research on the effects of DDAVP. Drs. Robinson and Vilhardt were also friends and in regular contact during this time. Robinson was also a paid Ferring consultant for some months before his job as research director in 1985 and then was again a paid

Ferring consultant from 1986-1989. After he left Ferring, the company sponsored a research program in his laboratory for about three years.

60. Dr. Barth, a Professor of Organic Chemistry and Biochemistry, also submitted a declaration in support of the '398 patent in 1990, which specifically addressed the Vavra reference. Dr. Barth worked on several paid research projects for Ferring as a paid consultant.

61. With an intent to mislead the PTO, Ferring knowingly provided the false and misleading declarations to the PTO in order to overcome the PTO's legitimate rejection of the '398 Patent Application. The fact that the PTO rejected the '398 Patent application three times before receiving the false and misleading declarations, indicates that but for Ferring's fraud, the '398 patent would not have issued. At all relevant times, Defendants understood that the '398 patent was procured by fraud and was therefore invalid and not capable of being properly listed in the Orange Book or enforced against a third party seeking to manufacture DDAVP.

62. Despite knowing that the '398 patent was procured by fraud, Defendants caused the '398 patent to be listed in the Orange Book. It was wrongful and illegal for Defendants to list the '398 patent in the Orange Book because, as Defendants knew or were recklessly indifferent in not knowing, there was no reasonable basis to believe that the '925 patent was valid or that a claim of patent infringement could reasonably be asserted on the basis of that patent because, *inter alia*, it was obtained by fraud and/or inequitable conduct.

63. As a result of Defendants wrongfully listing the '398 patent in the Orange Book, no generic manufacturer could submit an ANDA seeking approval to market a generic version of DDAVP in the United States without certifying either that its product would not be marketed in the United States until the expiration of each listed patent (called a "Paragraph III certification")

or that each listed patent was invalid or not infringed by the proposed product (called a "Paragraph IV certification").

Defendants File Sham Litigation Against Barr Laboratories

64. Barr Laboratories ("Barr") submitted ANDA No. 76-470 to obtain FDA approval to engage in the commercial manufacture, use and sale of generic desmopressin acetate oral tablets prior to the expiration of the '398 patent. Barr's ANDA contained a "paragraph IV certification" that the '398 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the product described in Barr's ANDA.[2]

65. Barr sent Ferring and Aventis letters dated October 29, 2002 notifying each that Barr's ANDA was received by the FDA, and that Barr's ANDA contained a "paragraph IV certification."

66. On December 13, 2002, Ferring and Aventis, within the 45 day period provided by Hatch-Waxman, filed a suit in the United States District Court for the Southern District of New York asserting that Barr infringed the '398 patent. Defendants, with full knowledge that the 398' patent had been procured by fraud and was unenforceable, proceeded with baseless patent infringement litigation in order to invoke the 30-month Hatch Waxman stay. This conduct had the effect of preventing DDAVP from coming to market and consequently of illegally extending Defendants' monopoly on DDAVP while the litigation progressed.

67. On February 7, 2005, the United States District Court for the Southern District of New York granted summary judgment to Barr, holding that Ferring had committed inequitable conduct by deliberately deceiving the PTO about the "non-inventor" declarations submitted with the '398 Patent Application. The Court found "clear and convincing evidence of an intent to

[2] Defendants had listed three additional patents in the Orange Book as claiming tablet form DDAVP, but these patents were not asserted against Barr.

mislead the examiners" and that "the deceit was practiced over a long period of time by more than one person and appears to have been outcome determinative." The Court found further that the "close and undisclosed long-standing associations between the declarants in this case and Ferring and Vilhardt should have been disclosed in order to avoid the foreseeable inference of fraud that logically arises from the undisputed facts of this case."

68. On the key issue of "but for" causation, the court found the following:

> Defendant contends, and this Court agrees, that the PTO must have relied substantially on these declarations, as there is no alternative explanation offered for the Board's final allowance of the claims after several prior rejections by the PTO.

The court stated "that three of the challenged declarations were submitted after several iterations of rejected attempts to obtain the patent's issuance speaks loudly as to motive and intent." The court concluded the "totality of the circumstances in this case reveals that no genuine issues of material fact as to inequitable conduct remain so as to preclude summary judgment" and found "the patent unenforceable on that ground."

69. Defendants litigation against Barr was objectively baseless and was brought solely for the anticompetitive purpose of delaying generic competition.

EFFECTS ON COMPETITION

70. Defendants exclusionary conduct has delayed generic competition and unlawfully enabled Defendants to sell DDAVP without being subject to generic competition. But for Defendants' illegal conduct, generic competitors would have begun marketing generic versions of DDAVP products much sooner.

71. If generic competitors had not been unlawfully prevented from earlier entering the market and competing with Defendants, direct purchasers, such as Plaintiffs, would have been

free to substitute a lower-priced generic for the higher-priced brand name drug and consequently would have paid substantially less for DDAVP.

72. By preventing generic competitors from entering the market, Defendants injured Plaintiffs by causing them to pay more for DDAVP than they otherwise would have paid. Defendants' unlawful conduct deprived Plaintiffs of the benefits of competition that the antitrust laws were designed to preserve.

73. To the extent that defining relevant product markets is necessary in this case, the relevant product market is the tablet form of DDAVP and its generic equivalents. The relevant geographic market is the United States. Defendants currently hold a 100% share in the relevant product and geographic markets. Accordingly, Plaintiffs and members of the Class continue to pay higher prices for DDAVP and its generic equivalents than they would otherwise have paid, as a result of Defendants unlawful extension of its patent monopoly through the conduct alleged herein.

Violations of Section 2 of the Sherman Antitrust Act

74. Plaintiffs incorporate by reference the preceding allegations.

75. Defendants knowingly and willfully engaged in a course of conduct designed to obtain patents fraudulently and extend unlawfully its monopoly power. This course of conduct included procuring the '398 patent by committing fraud and/or inequitable conduct before the PTO, improperly listing the fraudulently obtained '398 patent in the Orange Book, and improperly filing and prosecuting patent infringement actions against companies seeking to market competing DDAVP. Defendants' conduct was designed to delay the introduction of generic formulations of DDAVP into the market and was in violation of Section 2 of the Sherman Act.

76. Defendants intentionally and wrongfully maintained its monopoly power with respect to DDAVP in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. As a result of this unlawful maintenance of monopoly power, Plaintiffs and members of the Class paid artificially inflated prices for DDAVP.

77. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations. Their injury consists of having paid and continuing to pay higher prices for DDAVP than they would have paid in the absence of those violations. Such injury, namely overcharges, is of the type antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for the following:

A. Judgment in their favor and against Defendants for damages representing the overcharge damages sustained by Plaintiffs and the other members of the Class defined herein, trebled;

B. Pre- and post-judgment interest;

C. Costs of suit, including reasonable attorneys' fees; and

D. Such other and further relief as the Court deems just and proper.

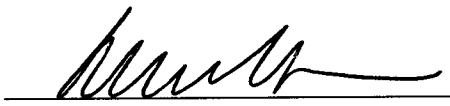
JURY TRIAL DEMANDED

Pursuant to Fed. R. Civ. P. 38(b), Plaintiffs demand a trial by jury of all of the claims asserted in this Complaint so triable.

Dated: February 18, 2005

Respectfully submitted,

COHEN, MILSTEIN, HAUSFELD & TOLL, P.L.L.C.



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